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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,185	12/14/2000	Danny Charles Bowman	2552-011	9139

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EXAMINER	
GAKH, YELENA G	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/737,185	BOWMAN ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 40-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21, 40-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on 02/16/05 is acknowledged. Claims 22-37 and 39 are cancelled. Claims 1-21 and 40-44 are pending in the application.

Response to Amendment

2. The rejection of the pending claims is sustained.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1-21 and 40-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All independent claims recite "a diagnostic specimen system comprising a population of biomedical specimen collection vessels" with the members of the population located in three different locations (a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory). According to 35 U.S.C. 101, patentable inventions are related to "any new and useful process, machine, manufacture, or composition". It is not clear, which category of this four the claimed subject matter belongs to. Also, "the subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. *Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a* ***particular structure*** *does not limit the scope of a claim or claim limitation.* The following are examples of language *that may raise a question as to the limiting effect of the language in a claim*: (A) statements of intended use or field of use, (B) "adapted to" or "adapted for" clauses, (C) "*wherein*" clauses, or (D) "whereby" clauses". (MPEP, Chapter 2106). It is not clear, what particular structure of the diagnostic specimen system is recited in the claims, besides a particular structure recited for collection vessels. Location of a part of the system at a specific place cannot be considered "a

particular structure" of the diagnostic system. Moreover, it is not clear, what will happen to the subject matter of the claim, if a part of the system, after being located at the specific location for some time, will be on the way to a different location (e.g. disposal), or on the way from the manufacturing site. Also, it is not clear, if the diagnostic system manufactured at the manufacturing site and still located at that site belongs to the claimed subject matter of the instant application. Moreover, it is not clear, if the same vessels should always be present at these particular locations, or these vessels are moving from one place to another? If the vessels are moving and changing their location, then how can such system be definite? Besides that, the vessel distribution facility (shelves with the vessels), the specimen collection facility (a special restricted area in the laboratory) and the specimen testing laboratory can be the same place.

The examiner concludes that since the location of the vessels does not further limit their structure, the limitation recited in the independent claims after "wherein" does not bear any patentable weight.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1-4, 6-7, 9-12, 14-15, 18-19, 21, 38, 41 and 44** are rejected under 35 U.S.C. 102(e) as being anticipated by Petrick (US 6,535,129B1).

Petrick teaches a method and business form for establishing a chain of custody, which comprises using a population of biomedical specimen (including toxicology specimen) collection vessels, each having wireless electronic memory tag 106 attached to the vessel for non-contact storage and retrieval of information; the tag includes a radio frequency transponder and stores

identification code for the vessel (col. 3, lines 18-36), as well as the information corresponding to the various forms 102: "in one example embodiment, RFID logger 108 may prompt the collection (or other) custodian 54 to input additional required information either manually (e.g., by writing the information onto form 102 using a pen or pencil) and/or automatically (e.g., by inputting information into a computer workstation or other electronic device via a keyboard, barcode scanner, optical character reader, speech recognition device and/or other data input means) (block 206). This additional information may become part of form 102 and/or a data record 110 that RFID logger 108 (and/or chip 106) records. RFID logger 108 may record the collected information onto form 102 and/or in an associated data record 110 (block 208)--which data record is associated with the particular RFID chip 106" (col. 3, lines 66-67 and col. 4, lines 1-12). Several types of forms are disclosed, which include information on a donor, a specimen and lab work required for the specimen, which all may be entered both manually and electronically. The specimen system further includes a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel (the label of US 5,976,014 recited by Petrick in col. 1, line 60 and col. 3, line 10), the label also serving as a tamper-indicating seal. The information is shared between different remote users: "as shown in FIG. 1, one interesting capability provided by system 50 is the ability to exchange data records 110 between custodian sites. For example, each RFID logger 108 may be coupled to the Internet, an enterprise intranet, a local or wide area network, the telephone network, or other data network 112. Data network 112 allows the various data loggers 108 to share automatically collected information and/or record the collected information to a centralized or distributed database facility 114 for archival and management purposes. Data network 112 allows data records 110 associated with an RFID chip 106 to "follow" the RFID chip in the sense that any node connected to the network may (if authorized) access a record tagged to the RFID chip" (col. 4, lines 45-57).

7. **Claims 1-2, 6-7, 9-10, 14-15, 18-19, 21, 40-41 and 44** are rejected under 35 U.S.C. 102(b) as being anticipated by Berney (US 5,777,303).

Berney discloses a diagnostic specimen system comprising a plurality of biomedical specimen collection vessels (test tubes) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "FIG. 5 shows an exemplary configuration of an electronic label 50 being accessible via radiofrequencies (RF) and which can

be used within the scope of the invention. As distinct from the preceding figures, which described devices using labels with contacts, it is of course also possible to use other kinds of electronic labels, **especially labels being read from distance**. This is the case for radiofrequency labels, which use a magnetic coupling" (col. 3, lines 26-33). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). "FIG. 4 shows an exemplary embodiment of means for reading/writing of a plurality of test tubes 40, 41, 42, 43 and 44 being equipped with electronic labels mounted on their supports. ... It is therefore possible, to control the entirety of the operations relating to the reading and to the transfer of information within the labels under concern with the aid of the keyboard 48 and via computer program menus, allowing to reduce error risks to a minimum. In order to perform, for example, a blood analysis, firstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central database into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient" (col. 2, lines 66-67 and col. 3, lines 1-25). There are no structural differences between "a diagnostic specimen container" and "a toxicology specimen container" the way they are recited in the claims indicated above. "A population of " biomedical specimen collection with "members" located at various locations of the specimen path is an intrinsic feature of the invention.

The methods for electronically storing information and recording information, recited in claims 18, 19 and 21 are inherently disclosed in the specification.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. **Claims 5, 8 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick.

Although Petrick did not specifically disclose storing data including the identity of a supplier of the container (vessel?) and its product information, it would have been obvious for anyone of ordinary skill in the art to include this information along with other data in Petrick's specimen system, because vessels (containers) from different suppliers may vary, and therefore such information is important for handling them properly, and because information on a supplier is always conventionally provided with products.

12. **Claims 16, 17, 20, 38, 42 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick in view of Hoffman et al. (US 5,613,012).

Although Petrick does not particularly teach encoding electronic signature in the electronic tag, she specifically indicates "tester's signature" in form 102, Fig. 3B.

Since Petrick indicated that all forms can be filled manually or electronically, it would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman for securing electronic transactions, because this is

an obvious improvement over hand-written document and because electronic submission of the forms suggested by Petrick assumes electronically encoded signature.

13. **Claims 2 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of disclosure of RD 421048 A.

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to use a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, in Berney's specimen container, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A and because this is one of "other kinds of electronic labels, especially labels being read from distance", mentioned by Berney.

14. **Claims 1, 6-7, 9-10, 14-15, 18-19 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney (US 5,777,303) in view of Bowman (US 5,135,313).

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "FIG. 5 shows an exemplary configuration of an electronic label 50 being accessible via radiofrequencies (RF) and which can be used within the scope of the invention. As distinct from the preceding figures, which described devices using labels with contacts, it is of course also possible to use other kinds of electronic labels, **especially labels being read from distance**. This is the case for radiofrequency labels, which use a magnetic coupling" (col. 3, lines 26-33). "Said electronic label 4 allows a registration of all

useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). "FIG. 4 shows an exemplary embodiment of means for reading/writing of a plurality of test tubes 40, 41, 42, 43 and 44 being equipped with electronic labels mounted on their supports. ... It is therefore possible, to control the entirety of the operations relating to the reading and to the transfer of information within the labels under concern with the aid of the keyboard 48 and via computer program menus, allowing to reduce error risks to a minimum. In order to perform, for example, a blood analysis, firstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central database into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient" (col. 2, lines 66-67 and col. 3, lines 1-25). There are no structural differences between "a diagnostic specimen container" and "a toxicology specimen container" the way they are recited in the claims indicated above.

The methods for electronically storing information and recording information, recited in claims 18, 19 and 21 are inherently disclosed in the specification.

Berney does not specifically disclose that the vessel is a tamper-indicating vessel.

Bowman discloses a chain-of-custody tamper-indicating bag for sealing a specimen taken to a remote location.

It would have been obvious for anyone of ordinary skill in the art to modify Berney's specimen collection vessel with tamper-indicating seal disclosed by Bowman for the same reasons indicated by Bowman, i.e. "so that any attempted tampering with the specimen will be indicated by at least a partial destruction of the seal" (col. 1, lines 7-8).

15. **Claims 3-4 and 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman, as applied to claims 1, 6-7, 9-10, 14-15, 18-19 and 21 above, and further in view of Stevens et al. (EP 1,004,359 A2).

Berney in view of Bowman do not specifically disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for anyone of ordinary skills in the art to improve Berney's container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container.

16. **Claims 5 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman and Stevens, as applied to claims 3 and 4 above, and further in view of the prior art disclosed by Leuenberger (US 5,314,421).

Although Stevens indicated that the label might contain product information, he is silent regarding information on a supplier.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to include information on the product supplier in the electronic tag the same way as indicated by Leuenberger for blood packs, because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and because information on a supplier is always conventionally provided with products.

17. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman, RD 421048 A, Stevens and Leuenberger.

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). He does not specifically indicate the container to be tamper-indicating. Bowman discloses tamper-indicating sealed container for transporting specimen to a remote location, which makes it obvious for anyone of ordinary skill in the art to apply the same tamper-indicating seal to Berney's container for the same reasons indicated by Bowman, i.e. to prevent intentional tampering of the seal.

Berney in view of Bowman do not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

Berney in view of Bowman and RD 421048 A do not disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

Berney, Bowman, RD 421048 A and Stevens do not specifically indicate that the tag contains information on the supplier.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to modify Berney-Bowman's container by introducing a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A; adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container; and adding information on identity of suppliers as indicated by Leuenberger, because, first this is a conventional information always provided with the products, and second, because the identity of the supplier may assist in the proper handling the container.

18. **Claims 16, 20 and 38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman, as applied to claims 1, 6-7, 9-10, 14-15, 18-19 and 21 above, and further in view of Fukuzaki (US 5,948,103).

Berney in view of Bowman do not disclose an encoded electronic signature of a donor of a toxicological specimen stored in the tag.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skills in the art to employ Fukuzaki's electronic security system, including encoded electronic signature security system, for Berney-Bowman's container when it is used for toxicological analysis, because the information contained in Berney-Bowman's electronic label should be secured in the case of toxicological

analysis, and Fukuzaki provides the most convenient way of securing the information with the encoded electronic signature, which should be the donor's electronic signature in this case.

19. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman, RD 421048 A, Stevens, Leuenberger, Fukuzaki and Coli et al. (US 6,018,713).

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). He does not specifically indicate the container to be tamper-indicating. Bowman discloses tamper-indicating sealed container for transporting specimen to a remote location, which makes it obvious for anyone of ordinary skill in the art to apply the same tamper-indicating seal to Berney's container for the same reasons indicated by Bowman, i.e. to prevent intentional tampering of the seal.

Berney in view of Bowman do not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

Berney, Bowman and RD 421048 A do not disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The

label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

Berney-Bowman-RD 421048 A and Stevens do not specifically indicate that the tag contains information on the supplier.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

Berney, Bowman, RD 421048 A, Stevens and Leuenberger do not disclose encoded electronic signature of the donor stored in the electronic tag.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skills in the art to modify Berney-Bowman's container by introducing a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A; adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container; adding information on identity of suppliers as indicated by Leuenberger, because, first this is a conventional information always provided with the products, and second, because the identity of the supplier may assist in the proper handling the container; and adding an encoded electronic signature of the donor of the toxicological specimen, because the information contained in improved Berney-Bowman's electronic label should be secured in the case of toxicological analysis, and Fukuzaki provides the most convenient way of securing the

information with the encoded electronic signature, which should be the donor's electronic signature in this case.

Response to Arguments

20. Applicant's arguments filed on 02/16/05 have been fully considered but they are not persuasive.

Regarding rejections under 35 U.S.C. 112, second paragraph. The examiner is not an expert in the art of civil engineering, and therefore cannot fully appreciate the analogy between the claimed population of vessels being distributed in different locations and a specific road in Alexandria. Moreover, such analogy does not seem to work in favor of the applicants: while the road can be in fact defined by the geographic location, since it should follow specific landscape, it does not seem to be the same for the plurality of vessels, which are perfectly similar independent on the place of their location.

The examiner considers the claimed population a plurality of vessels of a specific structure; the plurality of vessels is claimed in the prior art; however, even if only one vessel of such structure were claimed, the plurality of the vessels would be an obvious feature of the invention: see *In re Harza*, 124 USPQ 378 (CCPA 1960) (mere duplication of parts without any new and unexpected results is within the skill in the routineer in the art). All vessels are transportable, if they are not chained to the bench, with the chain being claimed as an additional structural element of the vessels, which is not the case for the instant application. The examiner is not aware of the patentable subject matter, which is bound to the geographic location. Binding the vessel population to a specific location raises a question of what happens to the patent protection of the vessel population as soon as it leaves this location. Does it become unprotected? The pending claims do not recite a place of production of the vessels. Does it mean that they are in a public domain at their manufacturing facility, and become patent protected at the vessel distribution facility?

Regarding rejections over the prior art: Petrick's reference disclosing a population of vessels of the same structure as the one disclosed in the instant invention and having the same practical utility intrinsically (*i.e.* inherently) comprises all features of the system, including distribution of the

vessels at appropriate facilities. Even a simple drawing in the patent (Figure 1) demonstrating a chain "collection custodian" - "intermediate custodian" - "laboratory", etc., indicates the distribution of the vessels within these facilities. Regarding the "same patentable invention": in claim 7 Petrick discloses "the business form of claim 1, wherein said wireless identification *device is adhered directly to the specimen or to a container containing the specimen*". The specification discloses "medical samples", "automated facility", etc., unambiguously indicating that the invention is related to a plurality of vessels (containers). The applicants might be aware, that it is a conventional US patent practice to define a plurality of objects by using a singular article "a" in claims. Thus, the examiner considers the reference claiming "the same invention as the application", and therefore the rule of 37 CFR 1.608 should be applied in this case (see MPEP §§ 2306-2308).

Regarding anticipatory rejections over Berney. The applicants might be aware of the fact that the words "inherently" and "intrinsically" are the closest synonyms meaning the same . The examiner wonders, why so much time had to be spent on looking for a synonym of the word used by MPEP, when it was quite obvious, what the examiner meant. In their arguments the applicants repeatedly refer to the location of the vessels. The intention of this referral is not apparent to the examiner. Again, if the applicants intend to patent their population of biomedical vessels at certain locations, then specific description of these locations and a distance between them should be claimed as well. As the examiner indicated in the previous arguments, in smaller facilities all three locations can be placed within one facility, or even one room, which renders the claims indefinite as to where the locations are placed. Regarding transportability of the vessels: as the examiner indicated before all vessels are transportable when no special structural elements restricting vessels from being transported or moved are claimed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/23/05

YELENA GAKH
PRIMARY EXAMINER